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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,356	10/06/2003	Chiaki Ishii	58600-8229.US00	5651

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PERKINS COIE LLP
P.O. BOX 2168
MENLO PARK, CA 94026

EXAMINER	
POPA, ILEANA	
ART UNIT	**PAPER NUMBER**
1633	

DATE MAILED: 09/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/680,356	ISHII ET AL.	
	Examiner	Art Unit	
	Ileana Popa	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 21* is/are pending in the application.

4a) Of the above claim(s) *13-18 and 21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of the invention of Group I, drawn to an array and of species of phosphatidylcholine, in the reply filed on 05/23/2006 is acknowledged.

Applicant withdrew claims 13-17 and 21 and cancelled claims 19 and 20. Claim 12 was amended to remove references to non-elected species.

Applicant notes that claim 18 was not included in the groups set forth by the restriction requirement. Since claim 18 is recites a method of manipulating lipid-bilayer regions, it falls within the subject matter of Group III, drawn to a method of manipulating lipid-bilayer regions on a substrate. Therefore, claim 18 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention (i.e., the invention of Group III), there being no allowable generic or linking claim.

Claims 1-12 are under examination.

Note: Change in Art Unit and SPE

The Examiner of record is now Ileana Popa, Art Unit 1633. Therefore, future correspondence should reflect such changes. Also, at the end of the Action is the information regarding the SPE and the Art Unit.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 9, 11, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Boxer et al. (WO98/23948).

Boxer et al. teach a surface detector array device comprising a substrate defining a plurality of distinct bilayer-compatible surface regions separated by one or more bilayer barrier regions, a bulk aqueous phase covering the substrate surface, a lipid bilayer expanse carried on each of the bilayer-compatible region, and an aqueous film interposed between each bilayer-compatible region and the corresponding lipid bilayer expanse, i.e., the aqueous film is interposed between the bilayer-compatible surface region and the lower surface of the corresponding bilayer expanse (claims 1 and 9) (p. 4, lines 5-12). With respect to the limitation of inner and outer bilayer surfaces, the method of Boxer et al. must necessarily result in expanses having an inner and an outer bilayer surface (compare also Fig. 1 of the international publication WO98/23948 with Fig. 1 of the instant application that both depict the same composition). Boxer et al. teach that the bilayer expanses may be modified such that they comprise lipids covalently coupled to biomolecules such as nucleic acids (i.e., oligonucleotide) that can be used to non-covalently attach other biomolecules to the bilayer via specific molecular interactions), i.e., Boxer et al. teach that biomolecules can be attached to the bilayer via

specific molecular interactions between complementary oligonucleotides (claim 1) (p. 4 bridging p. 5, lines 1-5, p. 16, lines 3-21). The bilayer-compatible surface regions may be formed of materials such as SiO_2, MgF_2, CaF_2, and mica (claim 11) and the bilayer expanse may comprise phosphatidylcholine (claim 12) (p. 4, lines 13-15 and 20-24). Boxer et al. also teach that one embodiment relates to sorting devices for biomolecules integrated or attached to the supported bilayer, wherein the device comprises barrier regions acting as two dimensional sieves having progressively smaller openings that are capable to sort the membrane-associated molecule by size, i.e., the array comprises descrete bilayer patches associated with the lipid bilayer expanses (claim 2) (p. 25 bridging p. 26 and Fig. 5). Since Boxer et al. teach all the limitation of the instant claims, the claimed invention is anticipated by the above-cited art.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 2, and 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boxer et al., as applied to claims 1, 2, 9, 11, and 12 above, in view of Cornell et al. (U.S. Patent No. 5, 874,316), Arnold et al. (U.S. Patent 5, 310, 648), or Bayerl et al. (U.S. Patent No. 6,051,372).

Boxer et al. do not teach the use of self-limiting lateral diffusion to separate the lipid regions from one another (claim 10).

Cornell et al. teach receptor membranes, wherein the monomers in the membrane may be prevented from diffusing laterally by selecting lipids that are crystalline at room temperature, which eliminates lateral diffusion (column 3, lines 25-29).

Arnold et al. teach an imprinted matrix, wherein the spatial organization of molecules in the substrate can be locked into place by a variety of means to form a structure incapable of lateral diffusion, for example by decreasing fluidity (column 7, lines 11-24, column 8, lines 1-10).

Bayerl et al. teach patterned surfaces, wherein the lateral diffusion can be prevented by switching the lipid bilayer phase to gel or crystalline and wherein the phase transition can be accomplished by adjusting one physical parameter, the temperature (column 4, lines 25-58, column 5, lines 4-25, column 7, lines 1-24, column 9, lines 32-53).

It would have been obvious to one of skill in the art, at the time the indention was made, to maintain the substrate orientation by limiting the lateral diffusion as taught by Cornell et al., Arnold et al., or Bayerl et al., with a reasonable expectation of success. One of skill in the art would have been motivated to do so because the use of self-limiting lateral diffusion to keep the lipid regions apart obviates the need for physical barriers on the substrate surface. One of skill in the art would have been expected to have a reasonable expectation of success in using any of the above-mentioned

techniques because the art teaches the successful use of such techniques to limit lateral diffusion between discrete lipid regions. Thus, the claimed invention was *prima facie* obvious at the time the invention was made.

6. Claims 1-7 and 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boxer et al., as applied to claims 1, 2, 9, 11, and 12 above, in view of both Boukobza et al. (J Phys Chem, 2001, 105: 12165-12170) and Niemeyer (DE 19902391, Abstract).

Boxer et al. do not teach discrete lipid bilayer patches associated with the lipid wxpanses, wherein the lipid bilayer patch is a vesicle comprising second biomolecules and wherein at least some of the patches have different second molecules (claims 2-7).

Boukobza et al. teach a novel immobilization technique for biomolecules comprising trapping single protein molecules inside lipid vesicles that are tethered to a supported lipid bilayer via biotin-avidin interaction, wherein the technique overcomes the problem of molecule-surface interaction (Abstract, p. 12165, column 2, second paragraph, p. 12166, column 1, Fig. 1). Boukobza et al. also teach that surface-tethered vesicles can be used for experiments on reconstituted membrane proteins and peptides , i.e., one or more second biomolecules associated with the patches (p. 12169, column 2, *Conclusion*). With respect to the limitation recited in claims 6 and 7, absent evidence of the contrary the protein or peptide molecules are able to freely move within the vesicle. Boukobza et al. do not teach tethering the vesicles to the supported lipid bilayer via patch-specific oligonucleotide hybridization or multiple biomolecules

associated with the vesicles. It would have been obvious to one of skill in the art, at the time the invention was made, to use the oligonucleotide hybridization as taught by Boxer et al. to tether vesicles to the array of separated lipid bilayers, with a reasonable expectation of success. The motivation to use oligonucleotides is provided by Niemeyer, who teaches that this technique allows for the parallel immobilization of different macromolecules coupled to different nucleic acids and therefore one of skill in the art would have known to use the technique to obtain expanses with different vesicle (i.e., patch) composition each vesicle being encoded by a specific oligonucleotide, as needed. The motivation to tether vesicles to the array of Boxer et al. is provided by Boukobza et al., who teach that vesicles are more suitable than the planar bilayers for studying functional membrane dynamic. One of skill in the art would have been expected to have a reasonable expectation of success to make and use such a composition because the art teaches the successful making and use of such compositions. Thus, the claimed invention was *prima facie* obvious at the time the invention was made.

7. Claims 1, 2, 8, 9, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boxer et al., as applied to claims 1, 2, 9, 11, and 12 above, in view of Shen et al. (PGPUB 2003/0148335).

Boxer et al. do not teach the identity of the biomolcule being determined from the sequence of the oligonucleotide (claim 8). Shen et al. teach the use of oligonucleotide identification tags for assaying the identity of non-nucleic acid targets, wherein the method can be used to identify any non-nucleic acid target associated with any surface

(Abstract, p. 2, paragraphs 0009 and 0012, p. 3, paragraph 0017). Shen et al. teach that the oligonucleotide tag can be identified without dissociation by hybridization analysis, wherein the tag is detected by contacting it with an array of complementary nucleic acids immobilized on a support (p. 3, paragraphs 0021 and 0023). Therefore, it would have been obvious to one of skill in the art, at the time the invention was made, to determine the identity of the biomolecule from hybridization analysis of its attached oligonucleotide with the complementary oligonucleotide present on the bilayer expanse, as taught by Shen et al. with a reasonable expectation of success. One of skill in the art would have been expected to have a reasonable expectation of success in using such a method because one of skill in the art would have had known the sequence of both oligonucleotides and the location of the complementary oligonucleotide in the lipid bilayer array. Moreover, the art teaches the successful use of oligonucleotide hybridization in determining the identity of oligonucleotide-tagged biomolecules. Thus, the claimed invention was *prima facie* obvious at the time the invention was made.

8. No claim is allowed. No claim is free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ileana Popa whose telephone number is 571-272-5546. The examiner can normally be reached on 9:00 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ileana Popa, PhD

JANET L. EPPS-FORD, PH.D.
PRIMARY EXAMINER